

APPENDIX A

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A method of <u>specifically</u> detecting [the presence or absence of] <u>a strain of Bacillus anthracis containing a surface array protein (SEQ ID NO:1)</u> in a test sample, the method comprising:

contacting a test sample with a [capture reagent] <u>first antibody that can</u> <u>specifically bind to Bacillus anthracis</u> surface array protein (SEQ ID NO:1) [that can bind to a Bacillus anthracis surface array protein], wherein the <u>first antibody</u> [capture reagent] forms a complex with the surface array protein if the surface array protein is present in the test sample; and

detecting whether the surface array protein is bound to the first antibody [capture reagent] with a second antibody that binds to the surface array protein, wherein the presence of surface array protein is indicative of the presence of Bacillus anthracis in the test sample.

- 5. (Amended) The method of claim 1 [4], wherein the <u>first or second</u> antibody is a [recombinant] <u>recombinantly produced</u> antibody.
- 6. (Amended) The method of claim 5, wherein the <u>first or second</u> antibody is a [recombinant] <u>recombinantly produced</u> polyclonal antibody.
- 7. (Amended) The method of claim 1 [5], wherein the <u>first or second</u> antibody is a monoclonal antibody.
- 10. (Amended) The method of claim 1, wherein the test sample is not cultured prior to contacting with the first antibody [capture reagent].
- [capture reagent] is immobilized on a solid support.

LEE et al.

Application No.: 09/754,947

Page 12

- 13. (Amended) The method of claim 11, wherein the <u>first antibody</u> [capture reagent] is immobilized on the solid support prior to contacting the <u>first antibody</u> [capture reagent] with the test sample.
- 19. (Amended) The method of claim 1 [17], wherein the second antibody [detection reagent] binds to a different epitope of the surface array protein than does the first antibody [capture reagent].
- 20. (Amended) The method of claim 17, wherein the <u>second antibody</u> [detection reagent] comprises a detectable label.
- 22. (Amended) A kit for detecting the presence or absence of *Bacillus* anthracis in a sample, the kit comprising:

a solid support upon which is immobilized a <u>a first antibody that can</u> specifically bind to [capture reagent that can bind to] a surface array protein <u>SEQ ID</u> NO:1) of *Bacillus anthracis*; and

a <u>second antibody</u> [detection reagent] which binds to the surface array protein.

- 25. (Amended) The kit of claim 22 [24], wherein the <u>first or second</u> antibody is a recombinant polyclonal antibody.
- 27. (Amended) The kit of claim 22 [24], wherein the <u>first or second</u> antibody [capture reagent] is a mixture of monoclonal and polyclonal antibody preparations.

LEE et al.

Application No.: 09/754,947

Page 13

APPENDIX B

CLAIMS PENDING WITH ENTRY OF AMENDMENT

1. (Amended) A method of specifically detecting a strain of *Bacillus* anthracis containing a surface array protein (SEQ ID NO:1) in a test sample, the method comprising:

contacting a test sample with a first antibody that can specifically bind to *Bacillus anthracis* surface array protein (SEQ ID NO:1), wherein the first antibody forms a complex with the surface array protein if the surface array protein is present in the test sample; and

detecting whether the surface array protein is bound to the first antibody with a second antibody that binds to the surface array protein, wherein the presence of surface array protein is indicative of the presence of *Bacillus anthracis* in the test sample.

- 3. The method of claim 1, wherein the *B. anthracis* strain is encapsulated.
- 5. (Amended) The method of claim 1, wherein the first or second antibody is a recombinantly produced antibody.
- 6. (Amended) The method of claim 5, wherein the first or second antibody is a recombinantly produced polyclonal antibody.
- 7. (Amended) The method of claim 1, wherein the first or second antibody is a monoclonal antibody.
- 8. The method of claim 1, wherein the test sample is collected from a site of suspected or threatened anthrax contamination.
- 9. The method of claim 8, wherein the test sample is collected using a cyclonic collection device.

LEE et al. PATENT

Application No.: 09/754,947

Page 14

10. (Amended) The method of claim 1, wherein the test sample is not cultured prior to contacting with the first antibody.

- 11. (Amended) The method of claim 1, wherein the first antibody is immobilized on a solid support.
- 12. The method of claim 11, wherein the solid support is a microtiter dish.
- 13. (Amended) The method of claim 11, wherein the first antibody is immobilized on the solid support prior to contacting the first antibody with the test sample.
- 14. The method of claim 1, wherein the method can detect *B. anthracis* at concentrations as low as about 10,000 cfu/ml.
- 15. The method of claim 14, wherein the method can detect B. anthracis at concentrations as low as about 5,000 cfu/ml.
- 16. The method of claim 15, wherein the method can detect B. anthracis at concentrations as low as about 1,800 cfu/ml.
- 19. (Amended) The method of claim 1, wherein the second antibody binds to a different epitope of the surface array protein than does the first antibody.
- 20. (Amended) The method of claim 17, wherein the second antibody comprises a detectable label.
- 21. The method of claim 20, wherein the detectable label is selected from the group consisting of a radioactive label, a fluorophore, a dye, an enzyme, and a chemiluminescent label.

PATENT

Application No.: 09/754,947

Page 15

22. (Amended) A kit for detecting the presence or absence of *Bacillus* anthracis in a sample, the kit comprising:

a solid support upon which is immobilized a a first antibody that can specifically bind to a surface array protein (SEQ ID NO:1) of *Bacillus anthracis*; and a second antibody which binds to the surface array protein.

- 23. The kit of claim 22, wherein the solid support is a microtiter dish.
- 25. (Amended) The kit of claim 22, wherein the first or second antibody is a recombinant polyclonal antibody.
- 26. The kit of claim 24, wherein the first or second antibody is a monoclonal antibody.
- 27. (Amended) The kit of claim 22, wherein the capture reagent is a mixture of monoclonal and polyclonal antibody preparations.
- 28. The kit of claim 22, wherein the kit further comprises written instructions for using the kit to determine whether a test sample contains *B. anthracis*.
- 29. The kit according to claim 22, wherein the kit further comprises a positive control that comprises a polypeptide that comprises an antigenic determinant of a *B. anthracis* surface array protein.

SF 1381979 v1